

Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA

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This document supersedes Guidance for Electrical Safety, Electromagnetic Compatibility, Mechanical Testing for Indwelling Blood Gas Analyzer Premarket Notification Submissions, issued June 28, 2000 and Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions, issued February 21, 2000



**U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Anesthesiology and Respiratory Devices Branch
Division of Cardiovascular and Respiratory Devices
Office of Device Evaluation**

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Additional Copies

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Class II Special Controls Guidance

Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

1. Purpose

This guidance document describes a means by which indwelling blood gas analyzers may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a legally marketed indwelling blood gas analyzer device should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness. This guidance document has been developed as a special control to support a change in classification from class III to class II. It identifies relevant material to include in a 510(k) premarket notification application. All FDA requirements regarding premarket notification submissions are not repeated in this document.

FDA has determined that special controls, when combined with the general controls and the specific information discussed in this guidance, are sufficient to provide reasonable assurance of the safety and effectiveness of indwelling blood gas analyzers. Thus, a manufacturer who intends to market a device of this generic type must (1) conform with the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification (510(k)) requirements described in 21 CFR 807.81, (2) address the specific risks to health associated with the indwelling blood gas analyzers, and (3) receive a substantial equivalence determination from FDA prior to marketing the device.

Device manufacturers may choose to submit an Abbreviated 510(k) when: (1) a guidance documents exists, (2) a special control has been established, or (3) FDA has recognized a relevant consensus standard. FDA believes an Abbreviated 510(k) is the least burdensome means of demonstrating substantial equivalence once a Class II Special Controls Guidance Document has been issued. See also **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**, <http://www.fda.gov/cdrh/ode/parad510.html>.

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including a description of the device, the intended use of the device, and the

proposed labeling for the device. An Abbreviated 510(k) should also include a summary report. In an Abbreviated 510(k), the summary report serves in place of the data required under 21 CFR 807.87(f) or (g). The summary report should describe the methods or tests used and the acceptance criteria applied to address the risks identified in this guidance document as well as any additional risks specific to your device. (See also 21 CFR 820.30 Subpart C Design Controls for the Quality System Regulation.)

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the document, **A Suggested Approach to Resolving Least Burdensome Issues**. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

2. Scope

The scope of this document is limited to the following devices:

- Indwelling Blood Carbon Dioxide Partial Pressure Analyzer
(21 CFR 868.1150, Product Code 73 CCC)
- Indwelling Blood Hydrogen Ion Concentration Analyzer
(21 CFR 868.1170, Product Code 73 CBZ)
- Indwelling Blood Oxygen Partial Pressure Analyzer
(21 CFR 868.1200, Product Code 73 CCE)

In addition to indwelling sensors, extracorporeal sensors, which are connected to indwelling sampling catheters, are also reviewed under these regulations and are within the scope of this guidance.

3. Identification of Risks to Health

FDA has identified four risks to health generally associated with the use of indwelling blood gas analyzers in the table below. You should also conduct a risk analysis to identify any other risks to health specific to your device. The premarket notification should describe the risk analysis method.

| Identified risk | Recommended mitigation measures |
|--|--|
| Electrical Shock | Section 9 |
| Electromagnetic Interference | Section 10 |
| Toxicity, Tissue Reactivity, Infection | Section 11 |
| Inaccurate measurement | Sections 12 and 13 |

4. Controls

FDA believes that the controls in the following sections of this guidance, when combined with general controls, will address the identified risks to health associated with the use of the indwelling blood gas analyzers. Manufacturers should demonstrate that their device complies with either the specific recommendations of this guidance or with an alternate means to address the above identified risks to health and to provide reasonable assurance of the safety and effectiveness of the device. If you have identified any additional risks, specific to your device, your 510(k) should identify those risks and the verification and/or validation activities required to address these risks.

5. 510(k) Content

An Abbreviated 510(k) that relies on a Class II Special Controls Guidance Document should contain the following:

- a coversheet prominently identifying the submission as an Abbreviated 510(k) and citing the title of the specific Class II Special Controls Guidance Document;
- items required under 21 CFR 807.87, including a description of the device (including detailed, labeled drawings and a complete discussion of the performance specifications), the intended use of the device, and the proposed labeling for the device.
- a summary report that describes how the Class II Special Controls Guidance Document was used to address the risks associated with the particular device type. You should describe the device performance requirements and discuss the hardware and software functions (see sections 6 and 7) provided to address the risks identified in this guidance document, as well as any additional risks identified in your risk analysis. The summary report should also briefly discuss the test method and acceptance criteria for each performance test (see sections 8-13) identified in the Special Controls Guidance document. (If a manufacturer elects to use an alternative approach to address a particular risk, or has identified risks additional to those in the guidance, sufficient detail should be provided to justify the approach or measures taken to address the additional risks.)

- If any part of the device design or testing relies on a recognized standard, the summary report should include:
 - a statement that testing will be conducted and that the product will meet specified acceptance criteria before marketing. For guidance, refer to our guidance **Use of Standards in Substantial Equivalence Determinations** <http://www.fda.gov/cdrh/ode/guidance/1131.html>, or
 - a declaration of conformity to the standard. For guidance, refer to **Guidance on the Recognition and Use of Consensus Standards** <http://www.fda.gov/cdrh/ost/guidance/321.html>. [Note: Testing must be completed before submitting a declaration of conformity to a recognized standard.]
- Indications for Use enclosure.

As an alternative to submitting an Abbreviated 510(k), you can submit a traditional 510(k) that includes all test reports, with supporting data, that address the performance issues presented in Sections 6- 13. Test reports should include methods, acceptance criteria, data, and conclusions sufficient to satisfy the requirements of 21 CFR 807.87 (f) or (g).

Note: Unless otherwise specified, testing to support either a traditional or Abbreviated 510(k) should be performed under the following conditions:

- Ambient temperature between 15 and 35°C
- Barometric pressure between 68 and 106 kPa
- Ambient humidity should be between 30 and 90%
- For line-powered devices, the line voltage between 110 and 125 V rms

6. Hardware Verification Activities

You should describe the steps taken to ensure that the hardware in the device meets its specifications. This information should include a concise discussion of the hardware verification process. You should specifically identify those verification activities associated with risks identified during the risk analysis. You should provide complete verification reports including:

- a detailed description of the test method and objective, including drawings of the test apparatus where appropriate;
- an explicit statement of the acceptance criteria for the test and how the criteria are selected;
- a discussion of how the test method simulates the intended environment of use;

- the results of the test;
- an analysis of the test results; and
- an explicit statement of any conclusions drawn from the test.

7. Software Validation Activities

Please refer to the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (hereafter, the *Software Guidance*), <http://www.fda.gov/cdrh/ode/software.pdf>, for a discussion of the software documentation that you should provide. FDA generally considers Indwelling Sensors to be of “moderate” level of concern for the purposes of software review.

We encourage you to take advantage of any recognized software standards and provide statements or declarations of conformity as described in FDA guidance, **Use of Standards in Substantial Equivalence Determinations**, already cited. Please visit the following website to search for the standards that have been recognized when a medical device contains software, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. We have created a supplemental data sheet for each software standard that we have recognized. The supplemental data sheet includes a table that indicates the documentation that should be included in a submission when a declaration of conformity is provided.

If the device includes off-the-shelf software, you should provide the additional information as recommended in the **Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices**, <http://www.fda.gov/cdrh/ode/1252.html>.

8. Visual and Audible Indicators and Alarms

Visual and audible indicators and alarms should conform to either:

| | | |
|---|----|---|
| ASTM F1463-93 (1999): Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care | OR | ISO 9703-1 (1992): Anaesthesia and respiratory care alarm signals -Part 1: Visual alarm signals AND ISO 9703-2 (1994): Anaesthesia and respiratory care alarm signals -Part 2: Auditory alarm signals |
|---|----|---|

9. Mechanical and Electrical Safety

The device should meet the electrical and mechanical safety requirements of *IEC 60601-1 (1988): Medical electrical equipment - Part 1: General requirements for safety* for Type BF equipment and *IEC 60601-1-1 Collateral Standard: Safety requirements for medical*

electrical systems. In addition, the device should conform with the additional recommendations in this section (9.1-9.3), which extend or supplement *IEC 60601-1* and *IEC 60601-1-1*.

9.1 Electrical Power Indicators

The device should have visual electrical power indicators to indicate that the device is energized. You should locate these indicators conspicuously on the device.

9.2 Auxiliary Output

If the device has an auxiliary output (i.e., data port, printer port, etc.), the operator's manual should clearly describe the proper connection of the auxiliary device to the auxiliary output. The device should operate within its specifications during and after application of a short-circuit applied to the auxiliary output.

Recommended Test Method

With the device in the standard operating mode, short-circuit all pins of the auxiliary output together. Verify that the device operates within its specifications during and after application of the short-circuit.

9.3 AC Power Grounding and Polarity

If the power cord for a line-powered device is not polarized, the device should operate within its specification when the power is connected in either polarity. The device should operate within its specification when operating from a grounded or an ungrounded power source (i.e., with the third-wire ground connected and with it disconnected at the plug end of the power cord).

Recommended Test Method

Power source conductors, patient-contacting circuits and transducer circuits should be adequately insulated to assure protection of the patient and device from overvoltages. Verify that the device operates within its specifications when operating from a grounded and ungrounded power source.

10. Electromagnetic Compatibility

Electromagnetic compatibility (EMC) is the ability of a device to operate properly in its intended environment of use without introducing excessive electromagnetic disturbances into that environment. EMC testing is described in *IEC 60601-1-2 (1993): Medical Electrical Equipment, Part 1: General Requirements for Safety, 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests*.

You should include a complete description of the EMC characteristics of the device, and information to verify those characteristics under the following circumstances:

- All devices should be tested with the third wire ground connected at the plug end of the power cord.
- Devices intended for home use should also be tested with the third wire ground disconnected at the plug end of the power cord.

When subjected to immunity tests, the device should operate within its specification during and after exposure to electromagnetic disturbances at the levels specified in this section. The immunity level should be adjusted *upward* by the rms sum of all errors in the measurement of that quantity unless otherwise stated. Patient simulators should be used to provide simulated normal stimulus to sensors during immunity testing. The device should not, as a result of a specified test condition: indicate an equipment alarm; exhibit temporary degradation or loss of function or performance that requires operator intervention or system reset; or exhibit loss or corruption of stored data. Any such failure during an immunity test should constitute failure of the test.

The device should meet the EMC requirements of *IEC 60601-1-2* edition 1. The following parts (10.2 - 10.5) specify levels that differ from those in *IEC 60601-1-2*. In addition, the device should conform with the additional recommendations in part 10.1, 10.6, and 10.7 of this section, which is not part of *IEC 60601-1-2*.

10.1 Magnetic Field Emissions

The device should be shown to operate within its specifications without emitting magnetic fields that exceed the Army, 7-cm distance limits given in RE101 of *MIL-STD-461D (1993): Requirements for the Control of Electromagnetic Interference, Emissions and Susceptibility*.

Recommended Test Method

With the device operating normally, measure emitted magnetic field strengths at the Army, 7-cm distance, according to RE101 of *MIL-STD-462D (1993): Measurement of Electromagnetic Interference Characteristics*. You should show that between 30 Hz and 100 kHz, the measured field strengths do not exceed the Army, 7-cm limits in RE101 of *MIL-STD-461D*.

10.2 Electrostatic Discharge

The device should be shown to operate within its specifications within five seconds of: air discharges of 2, 4 and 8 kV (both positive and negative) applied to insulating surfaces; and contact discharges of 2, 4 and 6 kV (both positive and negative) applied to conductive surfaces, to include any point on the device accessible to the operator or

patient. The device should also operate within its specification within five seconds of contact discharges applied to horizontal and vertical conducting planes in the vicinity of the device.

Recommended Test Method

The device should be tested using the method in *IEC 61000-4-2 (1999): Electromagnetic Compatibility (EMC)—Part 4-2: Testing and measurement techniques—Electrostatic discharge immunity testing*, with the following addition:

- Internally-powered devices, IEC Class II devices, and devices having circuits isolated from earth ground may be tested in a way that ensures that there is no appreciable charge retention between individual test discharges. Between individual test discharges, the electrical potential of the device may be equalized with that of the ground plane by temporarily attaching a ground strap incorporating two 470 k Ω resistors connected in series. The ground strap should be disconnected and moved at least 1 m away from the device during the application of individual test discharges.

10.3 Radiated Electromagnetic Fields

The device should operate within its specifications during and after exposure to amplitude-modulated electromagnetic fields with radiofrequency (RF) carrier frequencies between 80 MHz and 2.5 GHz and unmodulated field strengths of up to 3 V/m.

Recommended Test Method

The device should be tested using the method in *IEC 61000-4-3 (1995): Electromagnetic compatibility (EMC)—Part 4-3: Testing and measurement techniques—Radiated, radio-frequency, electromagnetic field immunity test*.

10.4 Voltage Dips, Short Interruptions and Voltage Variations

The device should operate within its specifications during and after power line dips to:

- less than 1% of nominal line voltage for 0.5 cycles of the power frequency;
- 40% of nominal line voltage for five cycles of the power frequency; and
- 70% of nominal line voltage for 25 cycles of the power frequency.

In addition, the device should operate within its specifications during and after voltage variations between 75 and 125% of the nominal line voltage.

Recommended Test Method

The device should be tested using the method in *IEC 61000-4-11 (1994): Electromagnetic compatibility (EMC)—Part 4-11: Testing and measurement techniques—Voltage dips, short interruptions and voltage variations immunity tests*.

10.5 Fast Transient Bursts

The device should operate within its specifications during and after transient bursts of 0.5, 1, and 2 kV (positive and negative) applied to AC power leads; and transients bursts of 0.25, 0.5, and 1 kV (positive and negative) capacitively coupled to signal and interconnecting leads at least 3 m in length. The pulse repetition rate should be 5 kHz.

Recommended Test Method

The device should be tested using the method in *IEC 61000-4-4 (1995): Electromagnetic compatibility (EMC)—Part 4-4: Testing and measurement techniques—Electrical fast transient/burst immunity test*. Patient cables should not be tested directly, but should be attached to the device during the testing of power and signal leads.

10.6 Power Frequency Magnetic Fields

The device should operate within its specifications during and after exposure to continuous, 60 Hz continuous magnetic fields having intensities as great as 3 A/m.

Recommended Test Method

The device should be tested using the method in *IEC 61000-4-8 (1993): Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 8: Power frequency magnetic field immunity test*, with the exception that a maximum display jitter of 0.6 millimeters is allowed for cathode ray tube displays.

10.7 Conducted Electromagnetic Energy

The device should operate within its specifications during and after exposure of each interconnecting cable, including power cables, to conducted electromagnetic energy at frequencies between 10 kHz and 100 MHz, at the levels specified in CS114, Curve #3 of *MIL-STD-461D*.

Recommended Test Method

The device should be tested using the method of CS114 of MIL-STD-462D, with the following modification:

- The carrier should be 80% amplitude-modulated with a 2 Hz sine wave.

The test should show that the device operates within its specifications during and after exposure to conducted electromagnetic energy at the levels specified in CS114, Curve #3 of *MIL-STD-461D*.

11. Biocompatibility and Sterility

Indwelling blood gas analyzers include a part that is inserted into an artery or vein. Manufacturers should evaluate the biocompatibility and sterility of the materials in the applied part that have direct contact with the patient. These materials should be considered to have circulating blood contact with prolonged contact duration. Please refer to the **Blue Book Memo, General Program memorandum G95-1**, <http://www.fda.gov/cdrh/g951.html> and **510(k) Sterility Review Guidance of 2/12/90 (K90-1)**, <http://www.fda.gov/cdrh/k90-1.html> to address the risks to health for indwelling blood gas analyzers. You should select tests appropriate for the duration and level of contact with your device. If *identical* materials are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of performing biocompatibility testing.

In addition, you should consider tests to detect chemical components of device materials that may be pyrogenic.

12. Performance Testing of Indwelling Blood Gas Analyzers

In characterizing the performance of the indwelling blood gas analyzer, you should conduct the performance studies as described in the following NCCLS standards:

- NCCLS Document EP5-A Evaluation of Precision Performance of Clinical Chemistry Devices
- NCCLS Document EP6-P Evaluation of the Linearity of Quantitative Analytical Methods
- NCCLS Document EP7-P Interference Testing in Clinical Chemistry
- NCCLS EP9-A User Comparison of Quantitative Clinical Laboratory Methods Using Patient Samples
- NCCLS Document EP10-A Preliminary Evaluation of Clinical Chemistry Methods

13. Clinical Information

Indwelling blood gas analyzers employing new technology, i.e., technology different from that used in a legally marketed indwelling blood gas analyzer, may warrant a clinical evaluation, in order to ensure that the particular device design meets user needs. In such cases, you should include a clinical validation plan, taking into consideration the issues discussed below.

Once the clinical validation study is completed, all documentation related to the study should be maintained in the design history file in accordance with 21 CFR 820.40(g). If the device does not meet the acceptance criteria outlined in the summary report, the device may not be marketed, and a new 510(k) submission will need to be submitted and cleared by the FDA.

The clinical validation plan should be sufficiently detailed to enable FDA to assess the ability of the design to meet user's needs. FDA may request additional information about aspects of the clinical plan, if it is not clear how your plan addresses the risks identified by FDA or your risk analysis, or if we need additional information to assess the adequacy of your acceptance criteria. We encourage you to discuss your clinical validation plan with us before submitting your 510(k).

The clinical validation plan should include the following elements:

1. Statistical hypothesis
2. Sample size, which should be adequate to permit reasonable confidence in the measure of all safety and effectiveness parameters
3. Statistical method(s)
4. Detailed description of the protocol you will follow. FDA recommends that you refer to "NCCLS Document EP10-A Preliminary Evaluation of Clinical Chemistry Method." Your protocol should:
 - a. Compare device performance to a legally marketed clinical laboratory blood gas analyzer. Well-controlled clinical laboratory measurements may be regarded as the actual value of the variable.
 - b. Include patients with a substantial range of variation, including hypercarbic and acidotic patients, and patients who are hypocarbic and alkalotic. These conditions may be found transiently in patients who are hyperventilated or are subjected to permissive hypercapnia, for example. You should select a sufficient number of patients to obtain values of pCO₂, pO₂, and pH distributed over the clinical range.

- c. Evaluate parameters relating to vessel perforation, occlusion, infection, clotting, and other adverse events that could reasonably be expected to occur. You should provide acceptance criteria for the rate of occurrence for each type of adverse event.
 - d. Evaluate parameters relating to accuracy, including bias (measured result minus actual value), precision, correlation coefficient, and sensor drift over time. The data points should be chosen in discrete time intervals to allow assessment of sensor performance over time. You should provide acceptance criteria for each of these parameters initially, and over time.
 - e. Evaluate device and comparative measurements made every 12 hours (\pm 4 hours) for the duration of the sensor life. At least 50 percent of the study patients should use the sensor for the maximum intended lifespan. You should provide acceptance criteria at the maximum intended life span of the sensor for each of the parameters cited above. Additional measurements may be taken as clinically indicated and should be included in the data set.
5. A sample of any case report form to be used for design validation.

Clinical design validation studies conducted after FDA determines that the device is substantially equivalent are exempt from investigational device exemptions (IDE) requirements in accordance with 21 CFR 812.2(c)(2). However, such studies must be performed in conformance with 21 CFR parts 50 and 56.

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, the study must be conducted under the IDE regulation (21 CFR 812). FDA has determined that these studies are significant risk, as defined in 21 CFR 812.3(m)(4); therefore, studies involving these devices do not qualify for the abbreviated IDE requirements of 21 CFR 812.2(b). In addition to the requirement of having an FDA-approved IDE, sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR 56) and informed consent (21 CFR 50).

14. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). All indwelling blood gas analyzers are prescription medical devices, and according to 21 CFR 801.109 must bear the following caution statement: “Caution: Federal law restricts this device to sale by or on the order of a physician.”

Although an indwelling blood gas analyzer is not an in vitro diagnostic, the information needed by a healthcare professional when using the device is similar. Labeling for an

indwelling blood gas analyzer should contain the information referred to 21 CFR 809.10, in addition to meeting the requirements of 21 CFR 801.1.

The following items are specific to this device class and should be included in the labeling:

- duration of use
- calibration intervals and procedures
- shelf life
- bias
- precision
- correlation coefficient
- known limitations or interferences
- statement that the device is non-pyrogenic

Once any clinical studies are completed, FDA recommends that you summarize the results of the study, including both performance and adverse events, in the labeling for the device.